

K001930

JUL 20 2000

## Attachment 4

### 510 (k) Summary

**SUBMITTER:** Nonin Medical, Inc.

**Address:** Nonin Medical, Inc.  
2605 Fernbrook Lane North  
Plymouth, MN 55447-4755

**Telephone:** 612.553.9968

**CONTACT PERSON:** Richard P. Bennett, Director of Regulatory Affairs

**DATE PREPARED:** June 19, 2000

**TRADE NAME:** Nonin® Model 2500 Pulse Oximeter

**COMMON NAME:** Pulse Oximeter

**SUBSTANTIALLY EQUIVALENT TO:**

The Nonin Model 8500 Pulse Oximeter

**DESCRIPTION OF THE DEVICE:**

**Comparison** The device description of the [Model 2500] is as follows: The Model 2500 Pulse Oximeter displays numerical values for blood oxygen saturation and pulse rate (Fig. 1) Because the Model 2500 Pulse Oximeter has no patient alarms, the user must frequently observe the SpO2 and pulse rate displays.

The Model 2500 typically will operate for 100 hours continuously between alkaline battery replacements. The Model 2500 requires no routine calibration or maintenance. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin saturation. (%SpO2) by measuring the absorption of red and infrared light passed through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine arterial saturation and pulse rate.

**Special 510(k):****Device Modification**

Oxygen saturation and pulse rate values are displayed on light-emitting diode (LED) digital displays. On each detected pulse, the pulse quality LED blinks. Patient pulse quality signals as good, marginal, or inadequate and are indicated by the pulse quality indicator blinking green, yellow, or red. This simple method gives the user a pulse-by-pulse visual indication of waveform signal quality without requiring the user to perform complex waveform analysis during critical patient care situations.

A sensor disconnect or malfunction is indicated by a lack of good pulse quality blinking and/or a dash to the left of the SpO2 value on the LED display. Ultimately, if adequate pulse signals are not received, the SpO2 and pulse rate numerical values will be replaced by dashes. When the batteries are low, the low battery indicator, a yellow LED, will be steadily illuminated. When the batteries are critically low, the low battery indicator will flash, the digital displays will go blank, and the pulse quality indicator will blink yellow or red, but not green.

**INDICATIONS FOR USE:****Indications for Use:**

The Nonin Model 2500 Hand Held Pulse Oximeter is intended to be used for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients in hospitals, ambulatory, home, and EMS (emergency medical service) environments. The Model 2500 is intended for spot checking and/or continuous monitoring when attended by a trained health care professional.

**SUMMARY OF TESTING:**

The Model 2500 Pulse Oximeter has followed (where applicable, the Reviewer Guidance for Premarket Notification Submission of November 1993, from the Anesthesiology and Respiratory Branch, Division of Cardiovascular, Respiratory and Neurological Devices. In addition, Nonin has conducted a Hazard Analysis and Risk Assessment, and developed extensive software/hardware procedures to confirm the performance of the product to the design requirements. Bench and clinical testing has been done to verify the performance of the device in a clinical environment. Verification studies have been conducted to ensure that the product requirements have been met.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 20 2000

Mr. Richard P. Bennett  
Nonin Medical, Inc.  
2605 Fernbrook Lane North  
Plymouth, MN 55447-4755

Re: K001930  
Nonin® Model 8500 Hand Held Pulse Oximeter  
Regulatory Class: II (two)  
Product Code: 74 DQA  
Dated: June 20, 2000  
Received: June 26, 2000

Dear Mr. Bennett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Richard P. Bennett

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Jim E. Dillard III", with a long, sweeping horizontal line extending to the right.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Special 510(k):

Device Modification

## Attachment 2

### Indications for Use Statement

510(k) Number:

K001930

Device Name:

Model 2500 Hand Held Pulse Oximeter

Indications for Use:

The Nonin Model 2500 Hand Held Pulse Oximeter is intended to be used for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate for adult, pediatric, and neonatal patients in hospitals, ambulatory, home, and EMS (emergency medical service) environments. The Model 2500 is intended for spot checking and/or continuous monitoring when attended by a trained health care professional.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number

K001930

Prescription Use ☒

(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

"SPECIAL 510(k): DEVICE MODIFICATION" NONIN MEDICAL INC MODEL 2500, HAND HELD PULSE OXIMETER